REMARKS

Reexamination and reconsideration of the application are requested.

The examiner's rejection of claims 1, 3, 6 and 8 as "obvious", under 35 U.S.C. 103, is respectfully traversed. The examiner rejects these claims as being unpatentable over Castel (US 5,413,550) in view of Watkin (non-patent literature).

The examiner, in the "Response to Arguments" section of the present office action, states that applicants, in their previous amendment, have not provided any support for arguing that the combination of Castel and Watkin does not disclose the claimed invention. Applicants will now provide such support.

Castel determines in vivo treatment time and/or in vivo ultrasound acoustic power from a mathematical function which includes only in vivo parameters and which does not include any in vitro parameters. The examiner admits on page 2 of the present office action that, "Castel does not disclose determining an in vivo treatment time (or ultrasound acoustic power) from a function of experimentally-determined in vitro treatment time (or ultrasound acoustic power)...." and that, "Castel also does not disclose that the mathematical function includes blood perfusion rate and patient tissue density".

Watkin on page 193, first column, has a "In Vitro Tissue Model" section consisting of a single paragraph which clearly indicates that the terminology "in vitro tissue model" refers to experiments done in vitro on excised porcine (pig) kidneys. Watkins in vitro experiments varied the in vitro ultrasound acoustic power from 300 to 3500 Wcm^{-2}, and for a given in vitro power, the in vitro exposure time was reduced until lesions could no longer be seen by eye on sectioning of the tissue. The relation between in vitro power (in vitro I_{SP} intensity) and in vitro treatment time (in vitro exposure time) and the minimum in vitro treatment time required to ablate patient tissue (produce a visible thermal lesion) was determined. See the paragraph labeled "In Vitro Tissue Model" in the first column of page 193 of Watkin. The results of the in vitro pig kidney experiments are plotted in figure 2 on page 192 of Watkin, wherein the small circles of the graph refer to the pig kidney and wherein the graph plots the in vitro treatment time (threshold time) to

ablate patient tissue versus the in vitro ultrasound acoustic power (intensity [I_{SP}]). See figure 2 and the bottom of the second column of page 193 of Watkin under Results – In Vitro Thermal Lesion Threshold.

It is important to note that the in vitro power is described as the free field [focal peak intensity] I_{SP} in figure 2 of Watkin (see the description of figure 2 at the bottom of page 192 of Watkin).

Watkin on page 193, first column, has a "Large-Animal Model" section consisting of four paragraphs which end in the second column of page 193 and which clearly indicate that the terminology "Large-Animal Model" refers to experiments done in vivo on living pigs. The in vivo ultrasound acoustic power (intensity [I_{SP}] was 1200 Wcm^{-2} for these in vivo experiments, and the in vivo treatment time (exposure time) was 3.5 seconds for these in vivo experiments. The accuracy of the in vivo power level was to within plus or minus 250 Wcm^{-2}, and the accuracy of the in vivo treatment time was to within plus or minus 0.5 seconds. See the four paragraphs labeled "Large-Animal Model" which begin in the first column of page 193 of Watkin.

It is important to note that the in vivo power referred to by Watkin is the in situ [focal peak intensity] I_{SP} which accounted for patient tissue density (i.e., which accounted for acoustic loss attributable to attenuation by the abdominal wall [skin, fat, muscle, and kidney]). See the second full paragraph of the second column of page 193 of Watkin.

Why did Watkin choose an in vivo treatment time of 3.5 seconds? Watkin chose an in vivo treatment time of approximately 3 seconds (3.5 seconds) because in vivo treatment time is reasonably approximately equal to in vitro treatment time for short treatment times of approximately 3 seconds or less where lesion formation is independent of organ perfusion based on evidence from computer models and small-animal studies (see the paragraph which begins near the bottom of the second column of page 194 and ends on the first column of page 195 of Watkin). Watkins chose at an in vivo treatment time equal to an in vitro treatment time of approximately 3 seconds (3.5 seconds) to avoid having to account for the effects of in vivo blood perfusion (organ perfusion) not present for in vitro patient tissue. Applicants believe it is

reasonable to argue that this shows Watkin did not chose an in vivo treatment time based on a mathematical function of in vitro treatment time which adjusts the in vitro treatment time to account for in vivo blood perfusion rate (as required by applicants' claims 1 and 6). If the examiner disagrees, it is noted that applicants' claims 1 and 6 also require that the in vivo treatment time be determined from a mathematical function of an in vitro treatment time wherein the mathematical function also includes patient tissue density. Watkin does not teach, suggest or describe this. It is not relevant to applicants' claims 1 and 6 for determining in vivo treatment time that Watkin may be said to determine in vivo intensity accounting for patient tissue density.

Why did Watkin choose an in vivo power level of 1200 Wcm^{-2}? Watkin chose 1200 because, based on visual observations, at power levels above 1500 Wcm^{-2}, lesions formed in front of the focus and were unpredictable in their size and shape (see the first full paragraph in the first column of page 195 of Watkin). As previously noted, Watkin did account for patient tissue density for his in vivo power. However, applicants' claims 3 and 8 also require that the in vivo ultrasound acoustic power be determined by a mathematical function of the in vitro ultrasound acoustic power, wherein the mathematical function also includes blood perfusion rate. Watkin does not teach, suggest or describe this. It is not relevant to applicants' claims 3 and 8 for determining in vivo ultrasound acoustic power that Watkin may be said to determine in vivo treatment time accounting for blood perfusion.

The examiner near the bottom of page 5 of the office action states that, "... Watkin teaches relating in vivo treatment time to in vitro treatment time and relating in vivo acoustic power to in vitro acoustic power, incorporating blood perfusion and patient tissue density. Applicants respectfully disagree. At best, as previously discussed, Watkin teaches relating in vivo treatment time to in vitro treatment time incorporating blood perfusion but not incorporating patient tissue density. At best, as previously discussed, Watkin teaches relating in vivo acoustic power to in vitro acoustic power incorporating patient tissue density but not incorporating blood perfusion.

It is clear that Castel and Watkin, taken alone or in combination, do not teach, suggest or describe the subject matter of applicants' claims 1, 3, 6 and 8.

The examiner's rejection of claims 2, 4, 7 and 9 as "obvious", under 35 U.S.C. 103, is respectfully traversed. The examiner rejects these claims as being unpatentable over Castel in view of Watkin and further in view of page 260 of Hill (non-patent literature). Claim 2 depends from claim 1, claim 4 depends from claim 3, claim 7 depends from claim 6, claim 9 depends from claim 8, and applicants' previous remarks concerning the patentability of claims 1, 3, 6 and 8 over Hill in view of Watkin are herein incorporated by reference.

Claims 2 and 7 require a specific equation mathematically relating the in vivo treatment time to form an in vivo lesion to the in vitro treatment time to form an in vitro lesion. The specific equation of clams 2 and 7 is not taught by page 260 of Hill. Even an equivalent equation to the specific equation of claims 2 and 7 is not taught by page 260 of Hill because no equation or combination of equations of page 260 of Hill mathematically relates, or even can mathematically relate, an in vivo treatment time to in vitro treatment time. The equations (such as equation 1) taught by page 260 of Hill do indeed relate parameters such as ultrasonic power and time and do indeed include terms such as for blood perfusion and tissue density, and such equations may be tested in vivo or in vitro, but such equations do not relate an in vivo ultrasonic power to an in vitro ultrasonic power or an in vivo time to an in vitro time.

Claims 4 and 9 require a specific equation mathematically relating the in vivo ultrasound acoustic power to form an in vivo lesion to the in vitro ultrasound acoustic power to form an in vitro lesion. The specific equation of clams 4 and 9 is not taught by page 260 of Hill. Even an equivalent equation to the specific equation of claims 4 and 9 is not taught by page 260 of Hill because no equation or combination of equations of page 260 of Hill mathematically relates, or even can mathematically relate, an in vivo ultrasound acoustic power to in vitro ultrasound acoustic power. The equations (such as equation 1) taught by page 260 of Hill do indeed relate parameters such as ultrasonic power and time and do indeed include terms such as for blood perfusion and tissue density, and such equations may be tested in vivo or in vitro, but such equations do not relate an in vivo ultrasonic power to an in vitro ultrasonic power or an in vivo time to an in vitro time.

Inasmuch as each of the rejections has been answered by the above remarks, it is respectfully requested that the rejections be withdrawn, and that this application be passed to issue. The Commissioner is authorized to charge any additional fees required or to credit any overpayment to Deposit Account No. 20-0809.

Respectfully submitted,

Douglas E. Erickson

Douglas E. Erickson

Reg. No. 29,530

Date: 2/11/08

THOMPSON HINE LLP
2000 Courthouse Plaza NE
10 West Second Street
Dayton, Ohio 45402-1758
(937) 443-6814